

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

FEASTER, *et al.*

Serial No.: 10/763,339

Filed: 26 January 2004

For: DEVICE FOR DETECTING, MEASURING AND
MONITORING THE ACTIVITIES AND
CONCENTRATIONS OF PROTEINS

Confirmation No. 7108

Art Unit: 1657

Examiner: Bin Shen

Atty. Dckt: 034047.003DIV1
WRAIR 00-23B

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Mail Stop AF

Dear Sir:

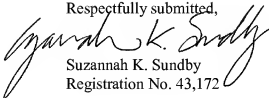
Applicant(s) respectfully request(s) review of the final rejection in the above-identified application. No amendments are being filed with this request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

I am attorney of record.

Respectfully submitted,



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REASONS FOR REVIEW REQUEST

The Claimed Invention

The claimed invention is a device for detecting, measuring or monitoring the activities of at least one protein in a test sample, where the protein belongs to a plurality of proteins which have similar or overlapping properties towards a plurality of substrates, which device comprises means for using a sensitivity coefficient as claimed to determine the activity or concentration of the protein. The claims require that the sensitivity coefficient be determined from a sensitivity coefficient sample by obtaining a plurality of inhibited dilutions of the sensitivity coefficient sample, wherein the plurality of inhibited dilutions comprise a plurality of concentrations of the protein which are partially to completely inhibited; exposing each inhibited dilution of the plurality of inhibited dilutions to each substrate; measuring the reaction rates between each uninhibited protein in each inhibited dilution and each substrate; calculating the linear relationships between the reaction rates of each uninhibited protein and each concentration of the sensitivity coefficient sample at infinite inhibitor concentration; and extracting each sensitivity coefficient of each substrate for each protein from the calculated linear relationships.¹

The Issues and Law

1. OFFICIAL NOTICE – Whether Official Notice supported by adequate evidence or an affidavit is required when applicants challenge a factual assertion, that a substrate for a protein is the same as the protein itself, made by the examiner.

LAW: Where an applicant challenges a factual assertion as not properly officially noticed or not properly based upon common knowledge, the examiner must support the finding with adequate evidence. *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test). If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2).

2. NONENABLING ART – Whether a non-enabling disclosure, Doretti et al., can not be used to anticipate the claimed invention.

¹ It is noted that claims to the method were issued in U.S. Patent No. 6,746,850 as the cited documents of record did not teach or suggest the sensitivity coefficient as set forth in the claims.

LAW: A patent claim “cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled.” *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

3. EACH AND EVERY LIMITATION – Whether an invention is novel where each and every limitation, means for determining the activity or concentration of a protein, is not taught.

LAW: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

4. INVENTION AS A WHOLE – Whether an invention is unobvious when the references cited by an examiner do not teach or suggest the invention, means for determining the activity or concentration of a protein using a sensitivity coefficient, as a whole.

LAW: In order to be obvious, the cited documents must teach or suggest the invention as a whole. See 35 U.S.C. 103(a), *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff’d mem.* 738 F.2d 453 (Fed. Cir. 1984), *KSR Int’l Co. v. Teleflex Inc.*, No. 04-1350 (U.S. 2007); and *Abbott Laboratories v. Sandoz, Inc.*, No. 05 C 5373 (N.D.Ill. 2007) (“KSR ... did not mention or affect the requirement that each and every claim limitation be found present in the combination of the prior art references before the [103 obviousness] analysis proceeds”).

5. PRINCIPLE OF OPERATION – Whether a proposed modification can not be made where it changes the principle of operation of the invention, from using a protein to measure a substrate to measuring the protein itself, disclosed in the primary reference.

LAW: If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. See *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

6. UNSATISFACTORY FOR INTENDED PURPOSE – Whether a proposed modification can not be made where it renders the invention of the primary reference unsatisfactory for its intended purpose, which is measuring a substrate instead of the protein.

LAW: If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

The Facts

1. OFFICIAL NOTICE – Applicants challenged a factual assertion implied by the Examiner, that a substrate for a protein is the same as the protein itself. In the Responses filed in the above-referenced application on 12 December 2007 and after, Applicants requested that the Examiner provide Official Notice that she holds that a substrate for a protein is the same as the protein itself in view of her interpretation and application of Doretto et al. See, for example, the Office Action of 31 August 2007, p. 2 (“[The biosensor] ... detects activities/concentrations of different substrates (read on as plurality of proteins ...” (emphasis added)). Instead of recognizing the difference between a substrate and a protein, the Office Action of 29 January 2008, the Examiner substantially reiterated the previous rejection, but without use of the word protein.

Thus, in the Response filed 29 April 2008, Applicants again explained the difference between a substrate and a protein and why the device of Doretto et al. does not teach or suggest structure or means capable of measuring a protein instead of substrate. In the Office Action dated 14 August 2008, the Examiner indicated on page 3, that the limitation of measuring a protein does not material change the device as it is interpreted as intended use instead of a structural limitation. In the Response filed 12 November 2008, Applicants again explained that the structure of Doretto et al., i.e. proteins immobilized on a membrane, is not the same as means or structure for assaying a protein. See page 5, last paragraph.

Since the structure of the device of Doretto et al. requires proteins immobilized on a membrane and the immobilized proteins and membranes appear to be asserted as anticipating the means for determining the activity or concentration of a protein according to the claimed invention, Applicants respectfully request Official Notice that the Examiner holds that a substrate for a protein is the same as the protein itself. If such Official Notice can not be made, then the rejections based on Doretto et al. must be withdrawn because Doretto et al. does not teach or suggest means for measuring the protein instead of the substrate.

2. NONENABLING ART – Doretto et al. does not enable the claimed invention. In particular, the device of Doretto et al. is incapable of measuring a protein. Specifically, the

device of Doretti et al. employs a given amount of a protein immobilized on a membrane to detect an measure a substrate for the protein. Since the Doretti et al. device employs immobilized protein as its binding and detection means, the Doretti et al. is incapable of measuring the protein itself in a sample. Nowhere does Doretti et al. teach or suggest any structure, means or method to measure the protein instead of the substrate. Thus, Doretti et al. does not provide any enabling description of a device having means for determining the activity or concentration of a protein.

3. EACH AND EVERY LIMITATION – Doretti et al. does not teach each and every limitation. Specifically, Doretti et al. does not teach any structure or means for determining the activity or concentration of a given protein using a sensitivity coefficient as set forth in the claims. See 1 & 2 above. Since each and every limitation of the instant invention is not taught, Doretti et al. does not anticipate the claims.

4. INVENTION AS A WHOLE – The combination of Doretti et al., Magnotti et al. and Ellman et al. do not teach or suggest the claimed invention as a whole. In particular, the cited references do not teach or suggest means, e.g. software and algorithms, for determining the activity or concentration of a protein using a sensitivity coefficient. Since the invention as a whole is not taught or disclosed, the claimed invention is unobvious.

5. PRINCIPLE OF OPERATION – Modifying the device of Doretti et al. to be capable of measuring proteins instead of substrates for the protein would change the principle of operation of the Doretti et al. device. Specifically, the principle of operation of the device of Doretti et al. employs immobilized proteins to measure substrates. Therefore, Doretti et al. can not be modified to measure proteins using immobilized substrates as doing so would change the principle of operation of the Doretti et al. device.

6. UNSATISFACTORY FOR INTENDED PURPOSE – Modifying the device of Doretti et al. to be capable of measuring proteins instead of substrates for the protein would render it unsatisfactory for its intended purpose. Specifically, the intended purpose of Doretti et al. is to measure substrates (not proteins). To modify Doretti et al. to be capable of measuring proteins would render it unsatisfactory for its intended purpose. Therefore, Doretti et al. can not be modified to measure proteins.

Applicants note that some of the arguments provided herein may not be deemed by the Panel to have been explicitly provided previously. Nevertheless, Applicants respectfully submit that submission of such explicit arguments would have been premature, i.e. Applicants had been waiting for the Examiner to be clear about whether she is holding that a substrate for a protein is the same as the protein itself and hence whether she interprets the means for detecting substrates, i.e. proteins immobilized on a membrane, in Doretti et al. to be the same as the claimed means for determining the activity or concentration of a protein or whether the disclosure of Doretti et al. is being modified to teach or suggest substrates immobilized on the membrane to detect proteins in order to construct precise rebuttal arguments based on the Examiner's clarification. However, due to the unwillingness of the Examiner to do so and the extensive prosecution thus far, Applicants respectfully request the Panel's kind consideration in order to advance prosecution.

Therefore, Applicants respectfully request that the review panel decide Finding 2 or Finding 3. If the review panel decides Finding 2, Applicants would appreciate a proposed amendment if appropriate.